Electromagnet Compatibility (EMC) for Neurostimulation Devices and Security Systems

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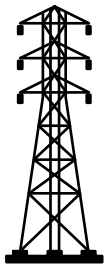
FDA EMC laboratory research helps ensure safe and effective neurostimulation devices through publication, standards, collaborations, and regulatory guidance and review.

What is EMI/EMC and Why the Concern?

Electromagnetic Interference (EMI)

Disruption of the electrically powered device function by Electromagnetic energy (EM)

- **Radiated EM (e.g. radio waves)**



- **Conducted (e.g. AC power surges)**

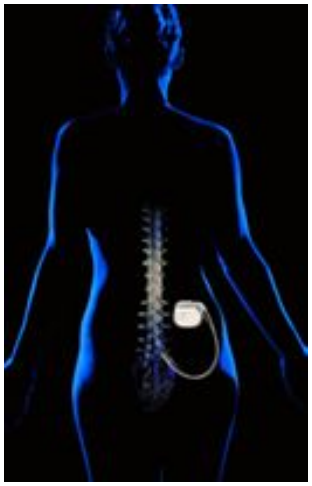
- **Electrostatic discharge (ESD)**

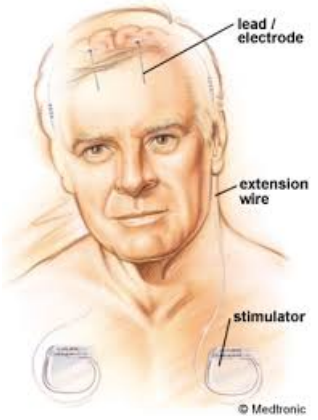
Electromagnetic Compatibility (EMC)

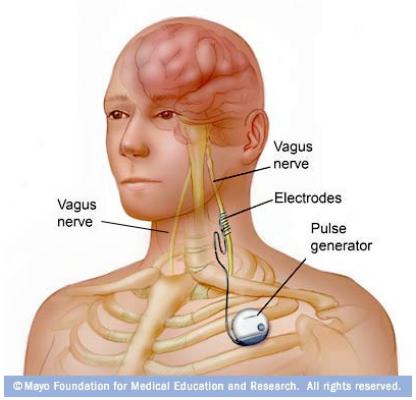
Device functions properly in its EM environment (immunity), and the device EM emissions do not cause EMI in other devices

EMI Concerns for Active Neurostimulator Devices

- Implantable-body worn neurostimulators
  - Spinal cord, Deep brain (DBS), Vagus nerve stimulator
- Hazards related to EMI
  - Over/under stimulation
  - Disturb control settings or telemetry communication
- Potential sources of EMI
  - Security systems: WTMD, HHMD, anti-theft (electronic article surveillance (EAS))
  - RFID, radio transmitters, diagnostic imaging (e.g., MRI), medical diathermy
  - Industrial/commercial environments

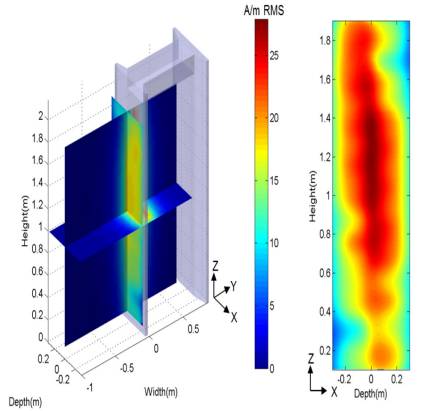




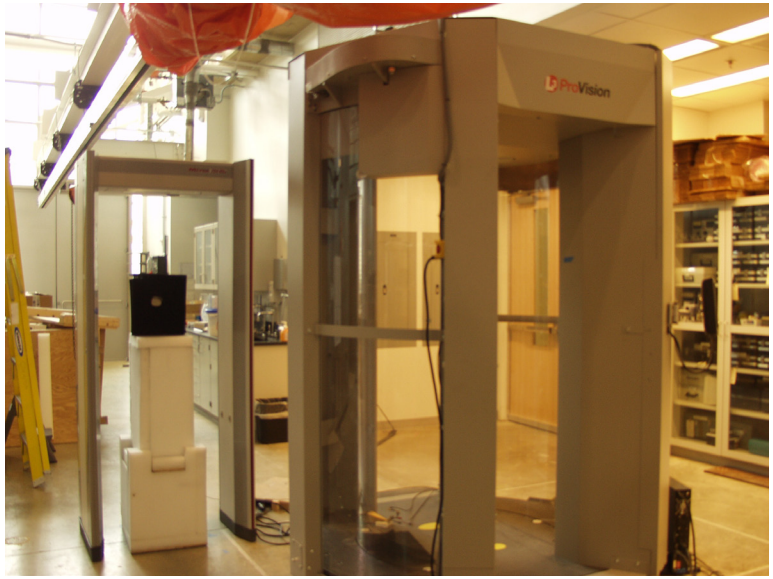


Leveraging Neurostimulator EMC Research

- Interagency agreement with TSA, DHS for AIT body scanner
- Collaborations with the medical device manufacturers



- Emissions measurements
- Develop test methods & perform exposure testing
- No effects seen on devices in AIT



- Findings are used in regulatory EMC guidance and reviews and national/international standards
  - ISO 14708-3
  - IEC 60601-1-2

Continuing Challenges for Medical Device EMC

- Changing electromagnetic environment, newer security systems & medical devices
- Continue to ensure devices are safe and effective for EMC
- Raise awareness of EMC/EMI
- Engage patients and caregivers
- How can EMC efforts be better engaged for patients?

Questions/Discussion

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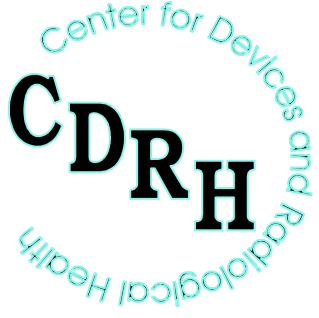


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